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DMHAS OOC IRB REVIEWER CHECK LIST – CONTINUING REVIEW

Title of Study: _____ Date of Review: _____

Reviewer: _____

Page 1 serves as research record face sheet

Checklist	y	n	n/a	Comment
☐Education in human subject protection has been documented for additional key personnel				
☐ Federal funding ☐ Other funding				
Recruitment site(s) include: ☐ State operated (facility must be notified of IRB actions) ☐ DMHAS funded ☐ Other				
Study site(s) include: ☐ State operated (facility must be notified of IRB actions) ☐ DMHAS funded ☐ Other				
☐ Study requires review by another institution's IRB ☐ Copy of other institution's current approval has been submitted				
☐ Study involves collecting and recording Identifying private information about individuals other than target participants				
☐ Study involves sharing data and/or biological material with entities outside of the study				
☐ Study involves the use of FDA regulated drugs or devices				
Study involves the following population(s): ☐ children ☐ pregnant women/fetuses ☐ prisoners ☐ mentally/cognitively impaired ☐ economically/educationally disadvantaged ☐ other potentially vulnerable population ☐ non- English speaking ☐ DMHAS staff ☐ non-DMHAS staff				
☐Waiver or alteration of consent was previously approved by IRB ☐Waiver of HIPAA Authorization was previously approved by IRB				
☐ Approval for changes is being requested				

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☐ Necessary study documents and materials are included (current protocol including any changes since last review, current consent form, recruitment material, instruments, ROI, questionnaires, scripts, highlighted changes where applicable, etc)				

Checklist	y	n	n/a	Comment
☐ Number of participants is consistent with IRB approval or discrepancy is adequately explained.				
☐ Non-computer data is maintained in a secure manner. ☐ Computer data is maintained in a secure manner.				
☐ Participant withdrawals indicate a possible problem and/or need for revision of the protocol or consent process				
☐ Adverse events and/or protocol deviations indicate a possible need for revision of the protocol and/or revision of the consent process				
☐ Recent literature or study findings thus far suggest a change in the level of risk or represent additional information that might impact a participant's decision to enroll or to continue in the study?				
☐ The risks and benefits appear to be consistent with those outlined in the initial approved protocol.				
☐ Is there any information that should be communicated to study participants?				
☐ The consent form(s) and process continue to adequately describe the study to participants.				
☐ Informed consent document, alone or in combination with additional release of information/authorization is in compliance with HIPAA authorization requirements.				
☐ Proposed changes are acceptable and do not adversely impact the risk/benefit ratio.				

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☐ The risk/benefit ratio is acceptable to continue the study				
☐ Other				